

<b>INFORMATION DISCLOSURE STATEMENT</b>	Atty. Docket No.: 51737US019	Serial No.: Unknown
	Applicant(s): Stefely, et al	
	Filing Date: Even Date Herewith	Group: 1619

JC868 U.S. PRO  
 10/07/8805  
 02/18/02

**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	SubClass	Filing Date If Appropriate
	2,457,238	12/28/48	Hunter et al.	—	—	
	3,079,299	02/26/63	Heilig	—	—	
	3,755,558	08/28/73	Scribner	—	—	
	3,773,919	11/20/73	Albert et al.	—	—	
	3,816,612	06/11/74	Schmidt et al.	—	—	
	3,887,699	06/03/75	Yolles	—	—	
	3,933,825	01/20/76	Fiscella et al.	—	—	
	4,010,196	03/01/77	Tsuk	—	—	
	4,011,312	03/08/77	Reuter et al.	—	—	
	4,683,288	07/28/87	Tanaka et al.	—	—	
	4,728,721	03/01/88	Yamamoto et al.	—	—	
	4,732,763	03/22/88	Beck et al.	—	—	
	4,801,739	01/31/89	Franz et al.	—	—	
	4,849,228	07/18/89	Yamamoto et al.	—	—	
	4,851,211	07/25/89	Adjei et al.	—	—	
	4,869,899	09/26/89	Burghart et al.	—	—	
	4,897,268	01/30/90	Tice et al.	—	—	
	4,997,643	5/31/91	Emmett, et al	—	—	
	4,981,850	01/01/91	Wade	—	—	
	5,236,702	08/17/93	Ritter et al.	—	—	
	5,300,255	04/05/94	Campbell et al.	—	—	
	5,302,693	4-12-94	Stricker, et al	—	—	
	5,384,133	01/24/95	Boyes	—	—	
	5,399,353	03/21/95	Bartnik et al.	—	—	
	5,424,063	06/13/95	Cardin et al.	—	—	
	5,478,921	12/26/95	Roby et al.	—	—	
	5,480,868	01/02/96	Kamei et al.	—	—	

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10/02/02  
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 10/02/02  
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	5,482,717	01/09/96	Fues et al.		
	5,536,445	07/16/96	Campbell et al.		
	5,538,721	07/23/96	Babcock et al.		
	5,567,431	10/22/96	Vert et al.		
	5,569,450	10/29/96	Duan et al.		
	5,618,911	04/08/97	Kimura et al.		
	5,631,015	05/20/97	Bezwada et al.		
	5,633,022	05/27/97	Stricker, et al		
	5,594,091	1/97	Igari et al.		
	5,648,096	7/97	Gander et al.		
	5,653,992	8/97	Bezwada et al.		
	5,665,394	9/97	Igari et al.		
	5,672,659	9/97	Shalaby et al.		
	4,997,643	5-3-91	Emmett, et al		
	5,874,064	2-23-99	Edwards, et al		
	5,633,002	05/27/97	Stricker et al.		
	5,871,771	2-16-88	Zierenberg, et al		
	6,126,919	10-3-00	Stefely, et al		

#### FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	SubClass	Translation
						Yes No
	2,017,851	11/30/90	Canada			
	39 16 020 A1	11/22/90	Germany (w/Eng. Language abstract)			X
	0 172 636 B2	02/26/86	EPO			
	0 330 180 A1	08/30/89	EPO			
	0 368 253 A2	5-16-90	EPO			
	368 571	5-16-90	Europe			

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0 372 777 A2	06/13/90	EPO			
0 521 455 A2	01/07/93	EPO			
400 522	12-5-90	Europe			
463 194	1-2-92	Europe			
468 199	1-29-92	Europe			
0 534 731 A1	3-31-93	EPO			
0 601 799 A1	06/15/94	EPO			
0 605 578 B1	07/13/94	EPO			
0 668 073 A2	08/23/95	EPO			
2 166 652 B	05/14/86	Great Britain			
2 234 896 A	02/20/91	Great Britain			
95-316272	12/05/95	Japan (Eng. language abstract only)			
95-316273	12/05/95	Japan (Eng. language abstract only)			
87/03197	06/04/87	WO			
88/09185	12-1-98	WO (Abstract)			
92/15340	09/17/92	WO			
94/15587	07/21/94	WO			
94/21228	09/29/94	WO			
94/21229	9-29-94	WO			
95/05153	02/23/95	WO			
95/15151	06/08/95	WO			
96/03983	02/15/96	WO			
97/40085	10-30-97	WO			
JP 9-59218	3-4-1997	Japan			X
JP 9-124778 A	5-13-1997	Japan			X

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

J | | | H.O. Alpar et al., "Preparation and Characteristics of Gentamicin-Containing Poly (Lactide-Co-Glycolide) Microspheres for Lung Targeting", J. Pharmacy & Pharmacology, 44, 1082 (Dec. 1992).

<b>EXAMINER</b> 	<b>Date Considered</b> 5/03
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02/18/03  
2003/01/02

2		M. Asano et al., "Biodegradability of a hot-pressed poly(lactic acid) formulation with controlled release of LH-RH agonist and its pharmacological influence on rat prostate", <u>Makromol. Chem., Rapid Commun.</u> , <u>6</u> , 509-513 (1985). J 968
		M. Asano et al., "In vivo controlled release of luteinizing hormone-releasing hormone agonist from poly (DL-lactic acid) formulations of varying degradation pattern", <u>Int'l. J. Pharm.</u> , <u>67</u> , 67-77 (1991).
		D. Bendix, "Some Remarks on the Broad Molecular Weight Distribution of Poly(D,L-Lactide-co-Glycolides) with Low INH Viscosities", <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> , <u>16</u> , 505-506 (1989).
		S. Berge et al., "Pharmaceutical Salts", <u>J. Pharm. Sci.</u> , <u>66</u> , 1-19 (Jan. 1977).
		R. Bodmeier et al., "The effect of the addition of low molecular weight poly(DL-lactide) on drug release from biodegradable poly(DL-lactide) drug delivery systems", <u>Int'l. J. Pharm.</u> , <u>51</u> , 1-8 (1989).
		A. Carrio et al., "Preparation and degradation of surfactant-free PLAGA microspheres", <u>J. Controlled Release</u> , <u>37</u> , 113-121 (1995).
		N. Celebi et al., "The preparation and evaluation of salbutamol sulphate containing poly(lactic acid-co-glycolic acid) microspheres with factorial design-based studies", <u>Int'l. J. Pharm.</u> , <u>136</u> , 89-100 (1996).
		P.P. DeLuca et al., "Biodegradable Polyesters for Drug and Polypeptide Delivery", <u>Polymeric Delivery Systems</u> ; ACS; Chapter 4, 53-77 (1993).
		G.A. Digenis et al., "Peptidyl Carbamates as Novel Elastase Inhibitors: Lung Delivery by Polyglycolic Acid Microspheres", <u>Pharm. Res.</u> , <u>3</u> , Abstract No. 85 (Oct. 1986)
		M. Dittrich et al., "Purification of biodegradable polymers and oligomers of aliphatic hydroxy acids", Abstract of Czech Patent No. CZ 278181 (15 Sept 1993) - Abstract only: CA122(16):188468y.
		S.E. Dunn et al., "Studies on In-Vitro Uptake by Kupffer Cells and the In-Vivo Biodistribution of a Range of Novel Polymeric Colloids", <u>J. Pharmacy &amp; Pharmacology.</u> , <u>44</u> , 1082 (Dec. 1992).
		N. Erden et al., "Factors influencing release of salbutamol sulphate from poly(lactide-co-glycolide) microspheres prepared by water-in-oil-in-water emulsion technique", <u>Int'l. J. Pharm.</u> , <u>137</u> , 57-66 (1996).

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2	H. Fukuzaki et al., "Synthesis of Copoly (D,L-Lactic Acid) with Relatively Low Molecular Weight and <i>In Vitro</i> Degradation", <u>Eur. Polym. J.</u> , <u>25</u> , 1019-1026 (1989).
	B. Guizou et al., "Investigation of <i>in-vitro</i> release characteristics of NSAID-loaded polylactic acid microspheres", <u>J. Microencapsulation</u> , <u>13</u> , 701-708 (1996).
	P.K. Gupta et al., "Development and Characterization of Aerosol Formulations of Biodegradable Microspheres for Targeted Delivery to the Lungs", <u>Pharm. Res.</u> , <u>7</u> , Abstract No. PT 6055 (Sept. 1990).
	K. Jamshidi et al., "Thermal characterization of polylactides", <u>Polymer</u> , <u>29</u> , 2229-2234 (Dec. 1988).
	I. Kaetsu et al., "Biodegradable Implant Composited for Local Therapy", <u>J. Controlled Release</u> , <u>6</u> , 249-263 (1987).
	K. Kimura et al., "Acid terminal-blocked poly(lactic acid) with good hydrolysis resistance", abstract of Japanese Patent No. 07316273 (5 Dec. 1995) - <b>Abstract only</b> : CA124(16):203400g.
	K. Kimura et al., "Polylactic acids and/or their copolymers", abstract of Japanese Patent No. 07316272 (5 Dec. 1995) - <b>Abstract only</b> : CA124(12):147775u.
	M. Kulkarni et al., "Characterization of Aerosol Formulations of Biodegradable Microspheres", <u>Pharm Res</u> , <u>8</u> , Abstract No. PT 6013 (Oct. 1991).
	M. Kulkarni et al., "Formulation of PLCA Microspheres as a Suspension Metered Dose Inhaler: Effect of Formulation Variables", <u>Pharm Res</u> , <u>11</u> , Abstract No. PDD 7141 (Oct. 1994).
	M. Kulkarni et al., "In-Vitro and In-Vivo Testing of Indium Labeled Poly (D,L-Lactide-Co-Glycolide) Microsphere Metered Dose Inhalers", <u>Pharm Res</u> , <u>11</u> , Abstract No. PDD 7149 (Oct. 1994).
	M. Kulkarni et al., "Stability of PLGA Microsphere Metered Dose Inhaler Formulations", <u>Pharm. Res.</u> , <u>11</u> , Abstract No. PDD 7150 (Oct. 1994).
	Y-L. Lai et al., "Sustained Bronchodilation with Isoproterenol Poly(Glycolide-co-Lactide) Microspheres", <u>Pharm. Res.</u> , <u>10</u> , 119-125 (1993).
	J.G.P. Lim et al., "Studies of Hydrophobic Microspheres for Controlled Pulmonary Drug Delivery", <u>J. Pharmacy &amp; Pharmacology</u> , <u>41</u> , 8P (Dec. 1989).
2	L. Masinde et al., "Nebulization of Poly (Lactic Acid) Microspheres From Aqueous Suspension", <u>Pharm. Res.</u> , <u>8</u> , Abstract No. PT6150 (Oct. 1991).

EXAMINER	Date Considered
	3/03

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J	J	L. Masinde et al., "Aerosolized Aqueous Suspensions of Poly(L-Lactic Acid) Microspheres", <u>Int'l. J. Pharm.</u> , <u>100</u> , 123-131 (1993).
J	J	S. Nagata et al., "Pharmaceutical dosage form design of copoly(lactic/glycolic acid) microspheres. Mechanism of in vitro release of gentamicin", <u>Yakugaku Zasshi</u> , <u>114</u> , 1005-1014 (1994). <b>Abstract only.</b> CA 122:196760.
		K. Nakamura et al., "Controlled release of poly-D-L-lactic acid containing bleomycin", <u>Anti-Cancer Drugs</u> , <u>6</u> , 483-487 (1995).
		K.H. Oh et al., "Plasticization of biodegradable films and microspheres with low molecular weight polymeric fractions", <u>J. Pharm. Sci.</u> , <u>76</u> , Abstract No. N 03-W-18 (November 1987).
		E.A. Poyner et al., "A comparative study on the pulmonary delivery of tobramycin encapsulated into liposomes and PLA microspheres following intravenous and endotracheal delivery", <u>J. Controlled Release</u> , <u>35</u> , 41-48 (1995).
		S. Ramanathan et al., "Controlled Release of Amiodarone from Poly L-Lactic Acid Microspheres", <u>Pharm. Res.</u> , <u>10</u> , Abstract No. PDD 7400 (Oct. 1993).
		K.M. Scholsky et al., "Characterization of Copolymers Fractionated Using Supercritical Fluids", <u>J. Applied Polymer Science</u> , <u>33</u> , 2925-2934 (1987).
		J.W. Tom et al., "Precipitation of Poly(L-lactic acid) and Composite Poly(L-lactic acid)-Pyrene Particles by Rapid Expansion of Supercritical Solutions", <u>J. Supercritical Fluids</u> , <u>7</u> , 9-29, (1994).
		T-Z. Tzou et al., "Comparing the Aerodynamic Particle Size of MDIs Measured by the Quartz Crystal Microbalance Cascade Impactor and the Andersen Cascade Impactor", <u>Pharm. Res.</u> , <u>12</u> , Abstract No. PT 6179 (Sept. 1995).
		R. Wada et al., "Lactic Oligomer Microspheres Containing an Anticancer Agent for Selective Lymphatic Delivery: I. <i>In Vitro</i> Studies", <u>J. Bioactive and Compatible Polymers</u> , <u>3</u> , 126-136 (April 1988).
		R. Wada et al., "New biodegradable oligoesters for pharmaceutical application", <u>J. Biomater. Sci., Polym. Ed.</u> , <u>7</u> , 715-725 (1996).
		D.A. Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery", <u>Science</u> , <u>276</u> , 1868-1871 (1997)
J	J	M.M. El-Baseir et al., "Preparation and Subsequent Degradation of Poly(l-lactic acid) Microspheres Suitable for Aerosolisation: A Physico-Chemical Study", <u>Int. J. Pharm.</u> , <u>151</u> , 145-153 (1997)

<b>EXAMINER</b> 	<b>Date Considered</b> 5/03
--	--------------------------------

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J	D.N. Leff, "Penn State, MIT Prove Large, Porous Aerosol Drugs Deliver Superior Therapy", <u>Bioworld Today</u> , <u>8</u> , No. 119, pp. 1, 3 (1997)
J	T. Niwa, "Aerosolization of Lactide/Glycolide Copolymer (PLGA) Nanospheres for Pulmonary Delivery of Peptide-drugs", <u>Yakugaku Zasshi</u> , <u>115</u> , No. 9, pp. 732-741 (1995)
	Y. Ogawa, "Injectable Microcapsules Prepared with Biodegradable Poly( $\alpha$ -hydroxy) Acids for Prolonged Release of Drugs", <u>J. Biomater. Sci. Polymer Edn.</u> , <u>8</u> , No. 5, pp. 391-409 (1997)
	V.A. Philip et al., "Effect of Surface Treatment on the Respirable Fractions of PLGA Microspheres Formulated for Dry Powder Inhalers", <u>Int. J. Pharm.</u> , <u>151</u> , 165-174 (1997)
	V.A. Philip et al., "In Vitro and In Vivo Respirable Fractions of Isopropanol Treated PLGA Microspheres Using a Dry Powder Inhaler", <u>Int. J. Pharm.</u> , <u>151</u> , 175-182 (1997)
	H. Sato et al., "Pharmacokinetic Study of Taxol-Loaded Poly(lactic-co-glycolic acid) Microspheres Containing Isopropyl Myristate after Targeted Delivery to the Lung in Mice", <u>Biol. Pharm. Bull.</u> , <u>19</u> , No. 12, 1596-1601 (1996)
	D.A. Edwards et al., "Large Porous Aerosols for Pulmonary Drug Delivery", <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , <u>24</u> , 67-68 (1997)
	J. Hanes et al., "Porous Dry-Powder PLGA Microspheres Coated with Lung Surfactant for Systemic Insulin Delivery Via the Lung", <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , <u>24</u> , 57-58 (1997)
	J. Hanes et al., "Porous Poly(D,L-Lactic-CO-Glycolic Acid) Microsphere Degradation and Release of Macromolecules", <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , <u>24</u> , 1027-1028 (1997)
	Wang, Nuo, et al, "Stabilization of Aspirin by Using a Lactic/Glycolic Acid Oligomer", American Chemical Society, papers presented at Las Vegas meeting, Vol. 38, No. 2, September 1997, pg 568-569.
J	Wang, Nuo, et al, Synthesis, Characterization, Biodegradation, and Drug Delivery Application of Biodegradable Lactic/Glycolic Acid Oligomers: I. Synthesis and Characterization. <u>J. Biomater. Sci. Polymer Edn</u> , Vol. 8, No. 12, pp. 905-917 (1997).

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<i>[Signature]</i>	Wang, Nuo, et al, Synthesis, characterization, Biodegradation, and Drug Delivery Application of Biodegradable Lactic/Glycolic Acid Oligomers: Part II. Biodegradation and Drug Delivery Application, <u>J. Biomater. Sci. Polymer Edn</u> , Vol. 9, No. 1, pp. 75-87-(1997).
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